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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,665	09/09/2003	Doug Hole	0-03-192	2000

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,665	HOLE ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/14/07, 3/7/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *4-8,10,12-14 and 16-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 11, 13, 15, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen (Croen, KD, *Evidence for an antiviral effect of Nitric Oxide*. J Clin Invest 91:2446-2452, 1993), further in view of US 6,265,420 to Lai.

In the specification and figures, Igo discloses the apparatus and method substantially as claimed by applicant. With regard to claims 1 and 15, Igo discloses a device and method for exposing a patient's blood to nitric oxide within an extracorporeal circuit. The method comprises the steps of providing an extracorporeal circuit 10 with an inlet 14 and outlet 48 that communicate with the patient, a fluid circuit, and at least one pump 22 (see FIGS 1-2). The method comprises the steps of circulating blood through the circuit and exposing the blood in the circuit to nitric oxide from a source (see column 4, lines 5-48).

Igo fails to disclose that the NO exposure is sufficient to reduce pathogenic content in the blood, but does disclose that the device comprises a means to control the administration of NO to the blood in the circuit in order to achieve a desired result. Croen teaches that NO exerts microbiostatic, microbiocidal, and antiviral effects on

pathogens (see p 2446). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify the method disclosed by Igo to expose the blood to an amount of NO sufficient to reduce pathogens in the blood in order to engage the antibiotic and antiviral effects of NO, as taught by Croen.

Igo discloses that the apparatus comprises a scavenger unit, but teaches that the scavenger unit scavenges NO from the carrier gas, and not patient blood (see Igo column 7, lines 39-45). However, Lai teaches that after NO administration, it is important to provide a NO scavenger in order to avoid undesirable side effects (see Lai column 2, lines 33-67, column 3, lines 45-55). Taken as a whole, the references reasonably suggest the method and apparatus claimed by applicant—an extracorporeal circuit for administering NO in an amount effective to reduce pathogens with a scavenger unit that removes excess NO from the blood to reduce unwanted side effects. All the claimed steps and elements are known in the art. One skilled in the art could have combined the known steps and known elements by known methods to yield the predictable result of an extracorporeal circuit for administering NO in an amount effective to reduce pathogens with a scavenger unit that removes excess NO from the blood to reduce unwanted side effects. Accordingly, the instantly claimed invention is unpatentable over the prior art of record.

With regard to claims 2-3, the Igo device and method may comprise a blood treatment component (such as a dialyzer, oxygenator, or heat exchanger) with one NO feed device located upstream of the treatment component (see column 4, lines 15-25).

With regard to claim 11, Igo discloses that the system and method may comprise the step of administering the NO with a carrier gas (see column 7, lines 25-35).

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,492 to Igo in view of Croen, in view of US 6,265,420 to Lai, further in view of McInnes et al (McInnes IB, Leung B, Wei, X-Q, Gemmell CG, and FY Liew. *Septic Arthritis Following* Staphylococcus aureus *infection in mice lacking inducible Nitric Oxide Synthase*. J Immun. 160: 308-315, 1998).

The cited prior art suggests the method substantially as claimed by applicant (see rejection above) with the exception of targeting septicemia during the method. McInnes discloses that NO production appears to reduce septicemia in mice, suggesting that NO exposure might be a successful treatment for sepsis (see page 313). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method suggested by the prior art to target septicemia as suggested by McInnes in order to control sepsis.

Response to Arguments

4. Applicant's arguments, filed 14 November 2007, with respect to the rejection(s) of the pending claims under Igo and Croen have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Igo, Croen, and Lai as presented above. Applicant argues that Igo does not teach a scavenger apparatus that acts upon circulating blood to scavenge free radicals from the blood. The Examiner

agrees and has added the Lai reference to teach the removal of free radicals from the blood.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Applicant's amendment changed the scope of the independent claims and all claims that depend therefrom. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
27 May 2008